

REMARKS

In the Office Action, Claims 1-25 are rejected under 35 U.S.C. § 103. Claims 1, 3, 8, 10, 12, 20 and 25 have been amended. Claim 2 has been cancelled without prejudice or disclaimer. Applicants believe that the obviousness rejections are improper or have been overcome as detailed below.

In general, a mineral that is bioavailable is capable of being transported through the intestinal wall and being absorbed into the blood stream. Bioavailability is a measure of the effectiveness of a ferric compound to be absorbed in the body. Bioavailability is, at least in part, a function of the solubility of the ferric compound. In general, relatively insoluble compounds have a lower bioavailability as they are less likely to be absorbed into the blood stream. Conversely, ferric fortificants that are soluble in water or dilute acids (e.g., ferrous sulfate) are more absorbable (i.e., they have a higher bioavailability). However, highly bioavailable compounds such as ferrous sulfate are disadvantageous in that they tend to be unstable and cause discoloration and off flavor.

The invention as claimed, including ferric sulfate as an iron fortificant, provides a stable complex for use in retorted products. In addition to the high stability, the iron in the complexes has substantially the same bioavailability as ferrous sulfate. Applicants respectfully submit that the claimed ferric-caseinate complex and the process of making same results in an improved product with surprisingly high bioavailability and without the disadvantages found in other iron fortificant compounds. For example, the complex of the claimed invention is obtained by a specific process that includes combining a ferric solution in a specific pH range and a casein solution at specific pH into a combined solution having a specific pH range. The pH of the casein solution is adjusted to avoid the formation of ferric hydroxide once the ferric solution is added thereto. Maintaining the pH of the ferric solution in the claimed range avoids the pH of the ferric-caseinate mixture dropping to the isoelectric point of casein such that precipitation of the casein may be significantly reduced. Therefore, the resulting complex has a reduced ability to cause deleterious effects, such as lipid oxidation, color degradation, and vitamin C degradation. This makes the complex an ideal vehicle for fortifying foods and beverages.

Claims 1, 3, 4, 8, 14-17, 19 and 20 are rejected as unpatentable over PCT Publication No. WO 98/21953 to Nash et al. ("*Nash*"). The Patent Office alleges that *Nash* on its own renders

obvious the claimed invention. Applicants believe that *Nash* is distinguishable from the claimed invention for a number of reasons.

Of Claims 1, 3, 4, 8, 14-17, 19 and 20, amended Claims 1, 3, 8, 14, and 20 are the sole independent claims. Claims 1, 3, 8, 14, and 20 have been amended to include an iron fortification system in powder form, the fortification system including a ferric-caseinate complex obtainable by, among other elements, dissolving a casein source in an aqueous liquid to provide a casein solution, adjusting the pH of the casein solution to about 5.4 to about 6.2, dissolving ferric sulfate in an aqueous liquid to provide a ferric solution, adjusting the pH of the ferric solution to about 5.4 to about 6.2, and combining the ferric solution with the casein solution and adjusting the pH to about 5.4 to about 7.0

First, *Nash* fails to teach or suggest an iron fortification system in powder form. Second, *Nash* does not provide a ferric-caseinate complex obtainable by dissolving ferric sulfate in an aqueous liquid to provide a ferric solution, as required by the claimed invention. Third, *Nash* does not teach or suggest pH levels of the casein solution or the ferric solution prior to combining the solutions together as required by the claimed invention, as even admitted by the Examiner. See, Office Action, pg. 2. As stated above, the claimed pH ranges prevent formation of ferric hydroxide and precipitation of casein upon combination. Applicants respectfully submit that a pH range for both solutions cannot be inferred from *Nash* based on the purported “lack of discoloration during thermal processing.” See, Office Action. *Nash* appears to imply that the lack of discoloration is due to high pressure continual thermal processing at ultra-high temperatures, rather than adjusting and combining multiple solutions at varying pH levels. Furthermore, *Nash* does not teach or suggest the advantages of adjusting the pH levels, as discussed above.

For at least these reasons, Applicants believe that *Nash* is distinguishable from the claimed invention and, thus, respectfully submit that *Nash* on its own fails to render obvious the claimed invention.

Claims 5-7, 9, 10, 13, and 22 are rejected as being unpatentable over *Nash* and further in view of U.S. Statutory Invention Registration No. H1620 to Dolan et al. (“*Dolan*”) and Myers et al. (“*Myers*”). With respect to Claims 5-7, 9, 10, 13, and 22, the Patent Office alleges that *Nash* in combination with *Dolan* and *Myers* renders obvious the claimed invention as defined by these

claims. Applicants believe that this rejection is improper based on at least the reasons set forth below.

Of Claims 5-7, 9, 10, 13, and 22, Claim 10 is the sole independent claim. Claim 10 recites a retorted liquid beverage that contains polyphenols and a stable iron fortification system in powder form. Claim 10 has been previously amended to include a ferric-caseinate complex obtainable by, among other elements, dissolving ferric sulfate in an aqueous liquid to provide a ferric solution.

As discussed above, *Nash* fails to teach or suggest a ferric-caseinate complex obtainable by dissolving ferric sulfate in an aqueous liquid to provide a ferric solution as required by the claimed invention. Further, Applicants respectfully submit that *Dolan* and *Myers* fail to remedy the deficiencies of *Nash*. Indeed, the Patent Office merely relies on *Dolan* for its alleged teaching regarding a chocolate flavored beverage mix that contains iron and on *Myers* et al. for its alleged teaching that chocolate is known to contain polyphenols. Therefore, *Nash*, in combination with *Dolan* and *Myers*, fails to teach or suggest a retorted liquid beverage that includes, in part, a ferric-caseinate complex obtainable by dissolving ferric sulfate in an aqueous liquid to provide a ferric solution as required by the claimed invention. In addition, *Dolan* and *Myers* do not provide a stable iron fortification system in powder form. Therefore, Applicants do not believe that *Nash*, *Dolan* and *Myers*, even if combinable, can be properly modified to cover the claimed invention, and, thus, this rejection should be withdrawn.

Claims 2, 12, and 18 are rejected as being unpatentable over *Dolan* in view of PCT Publication No. WO 98/42745 to Sakurai et al. ("*Sakurai*") and U.S. Patent No. 4,303,580 to Hidalgo et al. ("*Hidalgo*"). With respect to Claims 2, 12, and 18, the Patent Office alleges that *Dolan* in view of *Sakurai* and *Hidalgo* renders obvious the claimed invention. Applicants believe that *Dolan*, *Sakurai* and *Hidalgo*, even if combinable, are distinguishable from the claimed invention.

Of Claims 2, 12, and 18, Claim 12 is the sole independent claim. Amended Claim 12 recites a beverage powder which contains lipid and an iron fortification system in powder form. Claim 12 has been amended previously to include a ferric-caseinate complex obtainable by, among other elements, dissolving ferric sulfate in an aqueous liquid to provide a ferric solution.

The Patent Office admits that *Dolan* fails to describe an iron fortification system, let alone an iron fortification system in powder form that includes a ferric-caseinate complex as in

Claim 12 of the claimed invention. *Dolan* merely describes a flavored chocolate beverage mix, particularly a dry beverage mix that contains a number of ingredients, such as cocoa, protein and additional nutritional supplemental amounts of vitamins and minerals. See, *Dolan*, Abstract. Thus, *Dolan* on its own is clearly distinguishable from the claimed invention.

To allegedly cure the deficiencies of *Dolan*, the Patent Office has improperly relied on the combination of *Sakurai* and *Hidalgo*. Both references, however, fail to teach or suggest the ferric-caseinate complex of Claim 12. Indeed, *Hidalgo* discloses complexes other than the ferric-caseinate complex of Claim 12. For example, the oligo-element caseinate complex disclosed in *Hidalgo* includes calcium and nitrogen in addition to iron. *Hidalgo*, Example 6. Furthermore, *Hidalgo* fails to disclose the ferric oxidative state of iron as claimed. In fact, *Hidalgo* states that just because the oligo-element, such as iron, is in a certain state of oxidation to begin with, does not necessarily mean that it ends up in the caseinate exclusively in this same state of oxidation. *Hidalgo*, column 1, line 64 through column 2, line 3.

Moreover, the Specification at, for example, page 4, lines 22-29 provides concrete evidence of an unobvious difference between *Hidalgo* and the present invention. For example, the complex of the claimed invention is obtained by a specific process that includes combining a ferric salt and a casein solution at specific pH values such that effectively no ferric hydroxide is produced and no caseinate is precipitated. Surprisingly, the resulting complex has a reduced ability to cause deleterious effects, such as lipid oxidation, color degradation, and vitamin C degradation. This makes the complex an ideal vehicle for fortifying foods and beverages. *Hidalgo*, on the other hand, fails to disclose a product that exhibits these unexpected properties. The Board of Appeals in *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) emphasized that an unobvious difference between the claimed product and the prior art product is established if the claimed complex exhibits any unexpected properties compared with the product disclosed by the prior art. Therefore, *Hidalgo* fails to teach or suggest the ferric-caseinate complex of Claim 12, and, thus, the obviousness rejection should be withdrawn for at least these reasons.

Moreover, Applicants do not believe that the Patent Office can rely solely on *Sakurai* to remedy the deficiencies of *Dolan* and *Hidalgo*. As in *Hidalgo*, *Sakurai* discloses complexes other than the ferric-caseinate complex of Claim 12. *Sakurai*, for example, discloses carbonic acid-iron-casein complexes and/or hydrogencarbonic acid-iron-casein complexes. *Sakurai*,

column 1, line 66 through column 2, line 3. According to *Sakurai*, the carbonic or hydrogencarbonic acid is used to prevent the formation of iron hydroxides by the release of iron from otherwise weak iron/casein binding. *Sakurai*, column 1, lines 51-53. Therefore, even *Sakurai* distinguishes carbonic acid-iron-casein complexes and/or hydrogencarbonic acid-iron-casein complexes from the ferric-caseinate complex of the claimed invention. In addition, unlike the ferric-caseinate complex of Claim 12, *Sakurai* requires the combination of carbonic or hydrogencarbonic acid to form the complex disclosed in *Sakurai*. Accordingly, *Sakurai* fails to teach or suggest the ferric-caseinate complex of Claim 12, and, thus, the obviousness rejection should be withdrawn for at least these reasons.

Therefore, even if combinable, Applicants respectfully submit that one skilled in the art would not have been inclined to modify the cited art to purportedly arrive at the claimed invention.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention. Accordingly, Applicants respectfully request that the obviousness rejection in view of *Dolan*, *Hidalgo* and *Sakurai* be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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